In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 19-969V

UNPUBLISHED

COLLEEN BLOCK, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: April 26, 2021 Special Processing Unit (SPU); Table Dismissal; Onset; Influenza (Flu) Vaccine; Guillain-Barré syndrome (GBS)

Lia Obata Dowd, Dowd & Dowd, P.C., St. Louis, MO, for Petitioner.

Jeremy Fugate, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT AND CONCLUSIONS OF LAW DISMISSING TABLE CLAIM[1]

On July 3, 2019, Colleen Block filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleged that she suffered Guillain-Barré syndrome ("GBS") as a result of an influenza ("flu") vaccine administered on November 10, 2017. Petition at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

On June 2, 2020, Petitioner was ordered to show cause why this case should not be dismissed, because it appeared onset of her symptoms did not meet the Table's requirements. ECF No. 18. In reaction, Petitioner filed a brief and expert report on

[1] Because this unpublished Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all "§" references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

September 1, 2020. ECF Nos. 20-22 (collectively, "Br."). Respondent filed a responsive brief ("Opp.") on October 30, 2020. ECF No. 24. For the reasons discussed below, the Table version of Petitioner's claim is hereby dismissed – but Petitioner has offered just enough evidence to support a non-Table claim (although Respondent will be provided the opportunity to offer his own expert and/or brief the dispositive timing issue that could result in the Petition's total dismissal).

I. Relevant Procedural History

As noted, the case was filed in the summer of 2019.[3] ECF No. 1. On April 3, 2020, Respondent filed a Rule 4(c) Report challenging Petitioner's right to compensation. ECF No. 16. Respondent initially questioned the validity of Petitioner's GBS diagnosis, noting that her records lacked evidence of neurological and other clinical findings consistent with this condition.[4] Res. Report at 10-11. But Respondent also argued that even if Petitioner were found to have GBS, Petitioner's claim would not be viable based on the most likely date for onset of symptoms.[5] *Id*. at 12-14. Petitioner's medical records and affidavits placed the onset of her GBS within *24 hours* of vaccination – and thus outside the 3-42 day flu-GBS onset period set forth in the Vaccine Injury Table. *Id*. at 12. Moreover, Respondent asserted that Petitioner had not otherwise shown that the timing of her condition within one day of vaccination was medically acceptable to maintain even a causation-in-fact claim. *Id*. at 12-14.

I held a status conference with the parties on June 2, 2020. During the call, I noted that the record evidence appeared to establish onset of Petitioner's symptoms within approximately 24 hours of vaccination, as Respondent argued. ECF No. 18. Thus, a Table claim could not succeed. I also, however, raised issues with a causation-in-fact version of the claim, informing the parties I had in the past year dismissed such a claim where onset of GBS symptoms was too close in time to vaccination to be medically acceptable. *See Rowan v. Sec'y of Health & Human Servs.,* No. 17-760V, 2020 WL 2954954 (Fed. Cl. Spec. Mstr. Apr. 28, 2020) (finding that GBS is known to be mediated by autoantibodies produced via the adaptive immune system, and this process, if vaccine-induced, likely takes longer than three days to result in symptoms). Despite the above, I observed that Petitioner might still be able to produce evidence to establish a viable non-Table flu-GBS claim. ECF No. 18.

[3] Ms. Block later filed an Amended Petition on October 27, 2019 correcting citations used in the original Petition. ECF No. 9.

[4] Respondent additionally noted that a possible "functional (or conversion) disorder," as documented in Petitioner's medical records, might explain her symptoms. Res. Report at 11-12.

[5] Respondent also asserted that the records supported an alternative cause of Petitioner's GBS – specifically, a pre-vaccination history of diarrheal illness. Res. Report at 11.

I therefore issued an Order to Show Cause following the status conference directing Petitioner to file a response to Respondent's Rule 4(c) Report explaining why her claim – whether couched as a Table or causation-in-fact claim – should not be dismissed. ECF No. 18. Petitioner was additionally authorized to obtain an expert report in connection with her response. *Id*. Following the parties' submissions, I would determine whether dismissal of Petitioner's claim was appropriate. *Id*. The parties have briefed the matter as indicated above, and this case is now ripe for a determination.

II. Factual Background[6]

Ms. Block was administered a flu vaccine on November 10, 2017, at approximately 9:48 AM,[7] at Mercy Clinic Internal Medicine, her primary care provider. Ex. 4 at 153, 308-10. At the time of vaccination, Petitioner was 30 years old, with a prior medical history of Ehlers-Danlos syndrome, epilepsy, migraines, pseudotumor cerebri, pineal gland cysts, post-partum urinary dysfunction, and torn right hip labrum. Exs. 4 at 189, 358-59; 7 at 1187, 1204, 2261-62; 9 at 39-40.

Three days following her vaccination, on November 13, 2017, Petitioner returned to Mercy Clinic Internal Medicine with complaints of numbness, tingling, weakness, muscle aches, and shortness of breath. Ex. 4 at 169. Petitioner reported that "[o]n 11/11 her hands and feet went numb around 10 am." *Id*. She described worsening numbness and tingling thereafter that had progressed above her elbows and knees. *Id*. On examination, Petitioner was observed to have abnormal gait, general weakness, and diminished sensation. *Id*. at 172. She was directed to go to the Mercy Hospital emergency room for evaluation of GBS. *Id*.

Petitioner was admitted to the Mercy Hospital emergency room later that day. Ex. 7 at 1171. On intake, Petitioner was evaluated by Patrick Kane, M.D., who noted that Petitioner had received a flu vaccination three days earlier, and "[t]he following morning she woke with paresthesias and numbness to the bilateral hands and feet." *Id*. Dr. Kane recorded that Petitioner's symptoms had progressed proximally to the elbows and knees, and she was currently experiencing difficulty walking due to weakness. *Id*. Dr. Kane indicated that Petitioner would be admitted for continued management. *Id*. at 1177.

Petitioner was thereafter evaluated by Binu Mathew, M.D., an internist, on November 13, 2017. *Id*. at 1204. Dr. Mathew recorded a history of diarrhea for two-to-

[6] A more complete recitation of the facts can be found in the Petition, Respondent's Rule 4(c) Report, Petitioner's expert report, and the parties' briefing. Although I have reviewed all of the records filed to date, I have limited my discussion in this decision to the records most relevant to the issue of entitlement, with a particular focus on the onset of Petitioner's alleged injury.

[7] The medical record in connection with Petitioner's vaccination appointment indicates it was completed "11/10/2017 9:48 AM," and it was electronically signed **"**11/10/2017 9:49 AM." Ex. 4 at 308.

three weeks, and further noted that Petitioner had developed cramping, as well as upper and lower extremity numbness, the day following her vaccination. Ex. 7 at 1204. Dr. Mathew confirmed that a lumbar puncture had been completed and the results showed normal CSF protein. *Id*. Based on his examination, Dr. Mathew expressed concern for GBS and stated that "a recent diarrheal illness" might have been a trigger. *Id*. at 1208. However, Dr. Mathew indicated that Petitioner's neurological examination was "quite variable," which also raised concerns regarding a possible functional disorder. *Id*.

Petitioner subsequently underwent a neurology consultation with Gwyneth McCawley, M.D., on November 13, 2017. *Id*. at 1186. Petitioner stated that she had experienced sudden onset of numbness in her hands and feet the day following her flu vaccination that progressively worsened. *Id*. Petitioner indicated that her daughter had recently had a sinus infection, and Petitioner had episodes of diarrhea for the previous two weeks. *Id*. at 1187. On examination, Petitioner presented with weakness of the upper and lower extremities, decreased sensation, and diminished Achilles deep tendon reflexes. *Id*. at 1191. Dr. McCawley concluded that Petitioner's symptoms were most concerning for GBS; however, Dr. McCawley noted atypical features, including generally preserved reflexes and normal CSF protein. *Id*. at 1193. Petitioner was initiated on a course of IVIG. *Id*.

The next day, Petitioner was evaluated by Aaron Pickrell, M.D. *Id*. at 1211-13. Dr. Pickrell observed that Petitioner's presentation was concerning for GBS and stated that her recent diarrheal illness might have been a trigger. *Id*. at 1212. However, Dr. Pickrell recorded that "her neurological exam was quite variable, somatization?" *Id*. Petitioner was continued on IVIG with a plan for a five-day course of treatment. *Id*.

Petitioner had a follow-up neurology evaluation with Dr. McCawley on November 16, 2017. Dr. McCawley noted that Petitioner's symptoms were stable, but that she required assistance with standing and walking. *Id*. at 1245. Given Petitioner's atypical GBS features, Dr. McCawley ordered additional lab testing[8] and an EMG/NCV study. *Id*. at 1250-51.

The following day, Petitioner underwent an EMG/NCV study of her upper and lower extremities, which was normal.[9] Ex. 7 at 1285. Petitioner had a follow-up with Dr. McCawley later that day, who noted that normal EMG/NCV results could be seen in the

[8] Dr. McCawley ordered lab testing for anti-ganglioside antibodies to assess whether Petitioner had an autonomic variant of GBS that featured preserved reflexes. Ex. 7 at 1250. Dr. McCawley also ordered an autoimmune dysautonomia panel. *Id*. The lab testing for anti-ganglioside antibodies was negative, whereas the autoimmune dysautonomia panel was negative with the exception of elevated neuronal (V-G) and GAD65 Ab Assay. *Id*. at 1355-59, 1369-70.

[9] A notation associated with the EMG/NCV study indicated that Petitioner developed weakness of the upper and lower extremities with paresthesias "approximately 6 days ago" (i.e., November 11). Ex. 7 at 1285.

early course of GBS. Ex. 7 at 1265. Because Petitioner's presentation remained atypical, Dr. McCawley ordered an MRI of Petitioner's brain as well as a repeat MRI of Petitioner's cervical/thoracic spine[10] to confirm that there was no interval development of white matter lesion. *Id*. Dr. McCawley stated that, if the aforementioned imaging were normal, she would continue to believe the most likely diagnosis was GBS. *Id*. Petitioner underwent MRIs of her brain and cervical spine on November 18, 2017, which were normal and/or unchanged from previous studies. *Id*. at 1318-19. An MRI of Petitioner's thoracic spine revealed possible arachnoid cyst with ventral displacement of the spinal cord at T4-5 level with potential herniation. *Id*. at 1319-20.

Petitioner underwent a thoracic CT myelogram and repeat lumbar puncture on November 21, 2017. *Id*. at 1288, 1297, 1318. Later that day, Cyrus King, M.D., a neurosurgeon, noted that it was not "overtly apparent" that Petitioner had a spine herniation based on the myelogram. *Id*. at 1298.

On November 22, 2017, Petitioner underwent a neurology evaluation with Anna Conti, M.D. *Id*. at 1308-13. Dr. Conti recorded that Petitioner had received a flu vaccine and presented with weakness/sensory loss in the hands and feet, autonomic instability with abnormal sweating, and tachycardia starting the next day. *Id*. at 1308, 1313. Dr. Conti confirmed that Petitioner completed a five-day course of IVIG and had experienced improvement of her symptoms. *Id*. at 1313. On examination, Petitioner was observed to have horizontal nystagmus, generalized weakness of extremities, decreased sensation, and 2+ deep tendon reflexes. *Id*. Dr. Conti indicated that a thoracic disc herniation likely explained Petitioner's hyperreflexia, whereas Petitioner's clinical history and post-IVIG improvement were more consistent with GBS. *Id*. Dr. Conti stated that "[c]hronic demyelinating neuropathy are in differential, but [patient] does not feet [sic] temporal nor EMG criteria, as of yet." *Id*.

Petitioner was discharged from Mercy Hospital later that day. At the time of discharge, Robert Long, M.D., noted that Petitioner had a previous two-to-three week history of diarrhea, and she had begun experiencing progressive numbness starting the day following her flu vaccination. *Id*. at 1314. Petitioner's discharge diagnosis was seronegative GBS, and she was noted to be in improved condition. *Id*. at 1315, 1320. Petitioner was discharged to inpatient rehabilitation and physical therapy at Mercy Rehabilitation Hospital. *Id*. at 1314, 1323-24.

Following her admission to Mercy Rehabilitation Hospital, Petitioner was evaluated by Adam Edelman, M.D., an internist, on November 23, 2017. Ex. 9 at 39-46. Dr. Edelman provided a summary of Petitioner's hospital course and recorded that she had previously been undergoing outpatient therapy for right lower extremity weakness. *Id*. at 39.

[10] Petitioner had previously undergone an MRI of her cervical and thoracic spine on November 13, 2017. Ex. 7 at 1312-13.

Petitioner's diagnoses included GBS and recent diarrheal illness, the latter of which was noted as "possibly related to development of GBS." Ex. 9 at 46.

Petitioner received treatment at Mercy Rehabilitation Hospital from November 22, 2017 through December 5, 2017. At the time of discharge, Petitioner's lower extremity weakness had improved, although she continued to experience lower extremity tingling. *Id*. at 474, 485-86. Approximately one week later, on December 11, 2017, Petitioner had an outpatient physical therapy evaluation with Sara Baumgartner.[11] Ex. 8 at 2. It was noted that Petitioner began having lower extremity pain and paresthesia while running errands the day following her flu vaccination. *Id*.

At an outpatient follow-up neurology appointment with Dr. McCawley on December 15, 2017, Petitioner reported continuing sensory loss, difficulty moving her legs, and muscle spasms. Ex. 25 at 13. Dr. McCawley stated that she did not have a clear diagnosis of Petitioner's condition, although it was possible Petitioner had a GBS variant versus an autoimmune neuropathy. *Id*. at 21.

The next month, on January 26, 2018, Petitioner had another follow-up appointment with Dr. McCawley.[12] *Id*. at 41. Petitioner indicated that she was undergoing therapy and her symptoms had improved, but she experienced periods where her body and extremities went numb throughout the day. *Id*. at 42. Petitioner additionally reported new-onset dizziness over the previous six weeks. *Id*. Dr. McCawley ordered an EEG study[13] and directed Petitioner to continue therapy. *Id*. at 48.

On May 18, 2018, Petitioner returned to Dr. Hamm, her primary care physician, for treatment of a rash. Ex. 4 at 275-77. Dr. Hamm recorded that Petitioner's GBS was now back to normal, and she was continuing to follow with a neurologist. *Id*. at 277.

Petitioner had another follow-up appointment with Dr. Hamm on March 21, 2019. *Id*. at 407. Petitioner noted that, since her GBS onset, she had experienced numbness on the bottom of her feet, intermittent paresthesia in the extremities, and weakness. *Id*. at 408. Dr. Hamm's assessment was "GBS – with stable residual symptoms." *Id*. at 410.

At an appointment with Dr. Hamm one year later, on March 5, 2020, Petitioner again reported numbness, paresthesia, and weakness since the onset of GBS. Ex. 23 at

[11] Petitioner continued to receive physical therapy for treatment of the residual effects of GBS, in addition to symptoms relating to hyperextension/Ehlers-Danlos Syndrome and back/hip pain, through November 2018. *See* Exs. 8 at 8-268; 10 at 1-46.

[12] Petitioner had an intervening appointment with Dr. Hamm, her primary care physician, on December 22, 2017. Ex. 4 at 194-96.

[13] An EEG study completed on February 8, 2018 was normal. Ex. 25 at 60-61.

79. Dr. Hamm's assessment remained as "GBS – with stable residual symptoms." *Id*. at 81. There are no records of any subsequent treatment.

III. Expert Report

In conjunction with her written response to the show cause order, Ms. Block filed an expert report, dated September 1, 2020, from David M. Simpson, M.D. Ex. 13 ("Simpson Rep."). Dr. Simpson is a professor of neurology and the director of the Neuromuscular Division and Clinical Neurophysiology Laboratories at the Icahn School of Medicine at Mount Sinai, where he has served as an attending neurologist for the past thirty-seven years. Simpson Rep. at 1. Dr. Simpson indicated that his specialty area in neurology is neuromuscular disorders, and he has treated patients with GBS. *Id.* As shown in his CV, Dr. Simpson has authored several peer-reviewed publications on neurological disorders. Ex. 14 at 21-32.

Following a review of Petitioner's relevant medical records, Dr. Simpson opined that it was more likely than not that the administration of the flu vaccine on November 10, 2017 caused Petitioner's GBS. Simpson Rep. at 8. Dr. Simpson explained that there are several biologic mechanisms by which vaccines may lead to neurologic illness, including molecular mimicry, neurotoxic effect, immune complex formation, and loss of self-tolerance. *Id*. at 5-6. Regarding molecular mimicry in particular, Dr. Simpson asserted that this causal mechanism was widely accepted in the medical community in the development of autoimmunity generally and GBS specifically. *Id*. at 6. Dr. Simpson also cited to medical literature documenting occurrences of GBS following flu vaccination, and he opined that there was no persuasive evidence that Petitioner's GBS was caused by factors unrelated to the vaccine. *Id*. at 6-7.

Regarding the specific timing of Petitioner's GBS onset, Dr. Simpson asserted that many of Petitioner's medical providers recorded that Petitioner developed symptoms within 1-3 days of her receipt of the flu vaccine. Simpson Rep. at 7. However, Dr. Simpson stated that it was not unusual for patients to lack recall of the precise timing of onset when reporting symptoms retrospectively. *Id*. Even so, Dr. Simpson opined that the reported temporal onset of Petitioner's neurological symptoms as occurring the day after vaccination was within a medically-acceptable timeframe. *Id*.

In support of his opinion, Dr. Simpson cited to Y. Park et al., *Clinical Features of Post-Vaccination Guillain-Barré Syndrome (GBS) in Korea*, J. Korean Med. Sci. 2017 Jul;32(7):1154-1159, filed as Exhibit 22 (ECF No. 21-9) ("Park"). Simpson Rep. at 7. Park reviews post-vaccination GBS cases submitted for compensation to the Korean Advisory Committee on Vaccination Injury Compensation between 2002 and 2014 as part of the National Immunization Program in South Korea. Park at 1154-55. Park's authors note that of the 48 flu-GBS cases approved for compensation in South Korea during that

period, more than half of the cases (25) involved onset of neurological symptoms within two days of vaccination. *Id*. at 1155-56 and Fig. 1. Accordingly, Dr. Simpson opined that Petitioner's post-vaccination onset was medically acceptable because it fell within this timeframe. Simpson Rep. at 7. Park does not, however, discuss whether that timeframe was deemed medically acceptable, or what set of criteria was applied in awarding injury compensation in these Korean cases, although it does assert that the GBS diagnoses were mostly confirmed with commonly-applied diagnostic criteria deemed acceptable by the world-wide medical/scientific community. Park at 1155.

IV. Parties' Arguments

In her responsive brief to the show cause order, Ms. Block asserts that she was entitled to compensation for a GBS injury that was caused-in-fact by the flu vaccination. Br. at 1, 7. She also provided a summary of the relevant medical records and restated the assertions made in Dr. Simpson's report. *Id*. at 2-7.

In reply, Respondent reiterated that the record evidence preponderantly supported onset of Petitioner's GBS within approximately 24 hours after vaccination. Opp. at 8. Respondent asserted that the above timeframe is not medically acceptable even for a causation-in-fact claim, and he raised issues regarding the article Dr. Simpson cited to establish a proximate temporal relationship between vaccination and Petitioner's GBS. *Id*. at 10-12. Respondent otherwise argued that the facts of this case were analogous to my previous dismissal decision in *Rowan*, and he noted that Dr. Simpson had not explained how the biologic mechanisms he cited (e.g., molecular mimicry) could occur approximately 24 hours after vaccination. *Id*. For these reasons, Respondent argued that the petition should be dismissed.

V. Applicable Legal Standards

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i). The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). If petitioner establishes that the vaccinee has suffered a "Table Injury," causation is presumed.

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1279-80 (Fed. Cir. 2005) (referencing *Hellebrand v. Sec'y of Health & Human Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1351 (Fed. Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Federal Circuit has indicated that petitioners "must show 'a medical theory causally connecting the vaccination and the injury'" to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that "[t]here must be a 'logical sequence of cause and effect showing that the vaccination was the reason for the injury.'" *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. *See* 418 F.3d at 1278. *Althen* requires a petitioner

> to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

Id. All three prongs of *Althen* must be satisfied. *Id.*

Finding a petitioner is entitled to compensation must not be "based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion." Section 13(a)(1). Further, contemporaneous medical records are presumed to be accurate and complete in their recording of all relevant information as to petitioner's medical issues. *Cucuras v. Sec'y of Health & Human Servs.*, 993, F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in questions is considered less reliable than contemporaneous reports because the need for accurate explanation of symptoms is

more immediate. *Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993).

Analysis

I. Onset of Petitioner's GBS Likely Occurred Within One Day of Vaccination

In both Petitioner's responsive brief and Dr. Simpson's report, the onset of Petitioner's GBS was described as occurring within "several days" of her flu vaccination. Br. at 6-7; Simpson Rep. at 8. Dr. Simpson further proposed that her onset might have occurred generally within 1-3 days of vaccination, and that it is not unusual for patients to lack recall of the precise timing of onset when reporting symptoms retrospectively. Simpson Rep. at 7. Petitioner thus seems to make some effort to prove an onset that might arguably fall within the Table's 3-42 day period (even though she indicated in response to the Order to Show Cause that she does not assert a Table claim).

After reviewing the entire record, I conclude that the onset of Petitioner's GBS most likely occurred approximately 24 hours after vaccination. In making this determination, I find Petitioner's vaccination record and the progress notes associated with her first post-vaccination medical appointment to be especially probative. The vaccination record indicates Petitioner was administered the flu vaccine on November 10, 2017, at approximately 9:48 AM. Ex. 4 at 153, 308-10. Three days following her vaccination, on November 13, 2017, Petitioner presented to Mercy Clinic Internal Medicine with complaints of numbness, tingling, weakness, muscle aches, and shortness of breath. *Id*. at 169. She reported that "[o]n 11/11 her hands and feet went numb around 10 am" with subsequent worsening of her symptoms. *Id*.

Petitioner's reported onset of November 11, 2017 at 10:00 AM places her initial symptoms as occurring approximately 24 hours post-vaccination. In addition to being detailed and contemporaneous with the events described therein, these records comport with Petitioner's affidavits in describing her symptom onset. *See generally* Exs. 2-3. I further note that Petitioner's subsequent medical records similarly describe the onset of her GBS as occurring the morning of November 11, or (more generally) the day following her vaccination. *See* Exs. 7 at 1171, 1186, 1204, 1308, 1313-14; 8 at 2.

I give more weight to the above evidence than to Dr. Simpson's assertion that Petitioner's symptoms began in a more vague post-vaccination timeframe. I also do not find Dr. Simpson's statement regarding patient recall – i.e., that patients commonly lack recall of the precise timing of onset when reporting symptoms retrospectively – to be especially helpful in this matter. Indeed, Dr. Simpson did not cite any authority (e.g., medical literature) to support this statement. And at Petitioner's initial post-vaccination

medical encounters during which she described her symptoms, she was relating events that had occurred only two days earlier. *See Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993) (noting that contemporaneous medical records are generally presumed to be accurate and complete in their recording of relevant information regarding medical issues). It is reasonable to assume Petitioner accurately informed treaters when her symptoms began – especially since the record is consistent on this point. Accordingly, the cumulative record evidence preponderantly supports onset of Petitioner's GBS within approximately 24 hours after vaccination.

II. Resolution of a Causation-in-Fact Claim Will Require More Evidence

Because Petitioner's onset most likely began outside the Table's defined timeframe for a flu-GBS claim, no Table claim can succeed in this case. Petitioner, however, argues that the timeframe for onset, whatever it is, could still be sufficient to support a non-Table, causation-in-fact claim.

Here, if I ignore for the sake of argument some of Respondent's other objections, the success of Petitioner's non-Table claim would turn on the third *Althen* prong (i.e., whether Petitioner has established onset within a medically acceptable timeframe).[14] Dr. Simpson opined that the timeframe was medically acceptable, relying on Park for his assertion rather than his own experience or research treating GBS. Simpson Rep. at 7. Park is, however, not a particularly strong piece of evidence. Initially, although Park purports to document cases of GBS occurring within two days of receipt of the flu vaccine, it is unclear whether all of the short-onset cases in fact constituted GBS – indeed, the authors note that 18 of the 48 flu-GBS cases studied had a comparatively low level of diagnostic certainty. Park at 1158. The authors also acknowledge that pre-vaccination infection could not be excluded as a causative factor in approximately 10 percent of the total compensated flu-GBS cases. *Id*.

Park is also opaque as to the specific standards governing the award of compensation under the South Korean program. And it does not discuss whether a GBS onset less than two days post-vaccination is medically acceptable, or explain how a flu vaccine can cause GBS within that timeframe. Park therefore only establishes instances of a temporal association between vaccination and GBS – something recognized as not sufficient to meet a claimant's preponderant burden. *See Grant v. Sec'y of Health &*

[14] The first *Althen* prong is not reasonably in dispute, since there is preponderant evidence supporting a causal association between the flu vaccine and GBS, as recognized by numerous prior Program decisions. Respondent has, however, questioned the validity of Petitioner's GBS diagnosis, asserting that her records lacked evidence of neurological and other clinical findings consistent with this condition. Res. Report at 10-11. And Respondent noted possible alternative causes for GBS, such as the medical record evidence that Petitioner may have had a pre-vaccination illness (reflected as a course of diarrhea) that actually caused her condition (although Dr. Simpson raises objections in his report to this contention).

Human Servs., 956 F.2d 1144, 1148 (Fed. Cir. 1992) ("a proximate temporal association alone does not suffice to show a causal link between the vaccination and injury").

In addition, there are other sound reasons to question a one-day GBS onset. Previous flu-GBS non-Table claims adjudicated in the Program have mostly not succeeded where onset occurred earlier than three days after vaccination. *See generally Rowan,* 2020 WL 2954954, at *16-19 (36-hour post-vaccination onset of GBS for elderly individual was not a medically-acceptable timeframe to support non-Table claim); *Orton v. Sec'y of Health & Human Servs.*, No. 13-631V, 2015 WL 1275459, at *3-4 (Fed. Cl. Spec. Mstr. Feb. 23, 2015) (one-day onset of GBS after flu vaccine administration not substantiated with expert opinion). While these determinations do not control this outcome, they demonstrate that what is known medically/scientifically about the pathogenesis of GBS weighs against findings of flu vaccine causality when the onset is too close temporally to the vaccination event. Petitioner for her part has cited no contrary cases finding a one-day onset to be medically acceptable.[15]

Despite all of the above, it certainly is not the case in the Program that a claimant could *never* establish a non-Table flu-GBS claim based on a very short onset. And here, I find that Petitioner has offered *barely* enough evidence on the third *Althen* prong (in the form of the combined opinion of Dr. Simpson plus Park) to allow the claim to go forward for now. Despite my reservations about Park, it does provide some reliable evidence that a small group of individuals who likely had GBS experienced a short onset post-vaccination. Respondent, by contrast, has yet to provide rebuttal evidence that would undermine that conclusion. The citation to cases like *Rowan,* while highly relevant, do not do the job – for *Rowan* involved an elderly individual whose immune response was likely to take far longer than what she actually experienced. Petitioner herein, by contrast, was much younger.

My determination not to dismiss the claim at this time arises not from my view that Petitioner has a chance of success, but rather reflects my conclusion that the evidence adduced *to date* would, if unrebutted, barely support entitlement. Respondent will be given the opportunity now to file an expert report or other evidence rebutting the contention that a one-day onset is medically acceptable – and if he does so, the balance will likely tip against Petitioner.

[15] Those cases that have gone the other way are factually distinguishable in part. *See generally Lehrman v. Sec'y of Health & Human Servs.*, No. 13-901V, 2018 WL 1788477, at *14-19 (Fed. Cl. Spec. Mstr. Mar. 19, 2018). The *Lehrman* petitioner, however, was found to have a pre-vaccination history of upper respiratory infection which, in combination with the flu vaccination, was found to have resulted in an upregulation of the petitioner's immune system that led to a rapid onset of GBS. *Id*. Here, Petitioner has not presented comparable evidence to establish that her GBS onset within 24 hours of vaccination was medically acceptable under the specific facts of this case.

Conclusion

Petitioner cannot proceed on a Table claim in this matter, and therefore any such claim is dismissed. Petitioner's non-Table claim, however, may proceed. Respondent shall file an expert report and/or any other evidence bearing on the third *Althen* prong[16] on or before June 30, 2021. Petitioner shall thereafter be afforded the opportunity to file a rebuttal report from Dr. Simpson, and then I shall decide the claim based on these additional filings.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[16] The case's disposition is still likely to turn on the timeframe issue, and therefore the parties are advised to limit additional briefing or filings to it. If I ultimately determine dismissal is still inappropriate, I will set the matter for hearing, at which point other issues raised about the claim (such as alternative cause) can be addressed.